

## **REMARKS**

Claims 1-13 are being examined and all have been rejected. Applicant responds as follows:

### **Objection to the Specification**

The specification was objected to with respect to the status of the parent application. In response, the priority claim has been updated to reflect that the parent application is now an issued patent.

### **Rejection Under 25 U.S.C. 112, ¶2**

Claims 1-13 were rejected under 35 U.S.C. 112, paragraph 2, as being indefinite.

Claim 1 was rejected as vague for use of the term "binder" without description of what it binds to. In response, Applicant has amended claim 1 to clarify that the binder is specific for a labeled detection compound.

Claim 1 was rejected as vague for use of the term "said measurement" without apparent antecedent basis. In response, Applicant has amended claim 1 to recite "said comparing" in place of "said measurement" wherein "comparing" appears at the beginning of step (c).

Claim 1 was rejected as confusing at lines 10-11 of the claim because it recites using only the working electrode whereas the previous lines require use of both the working and reference electrodes to determine the potentiometric response. In response, Applicant notes that the claim appears to be clear on its face, in that a single "working

electrode" is sufficient for the recited process, which electrode is different from the reference electrode. Applicant notes that the term "single working electrode" means a single "working electrode" and not merely a single electrode that works.

Claims 3-5 were rejected as vague for use of the term "said labeled detection compound" without proper antecedent basis. In response, Applicant has amended claim 1 to provide antecedent basis.

Claim 8 was rejected as vague for use of the phrase "said electrocatalytic enzyme" without proper antecedent basis. In addition, the Examiner suggests a grammatical change. In response, Applicant has amended claim 1 to provide antecedent basis. Applicant has also amended claim 8 to add the word "is" after "enzyme."

Claims 9 and 10 were rejected as vague for recitation of "said electrocatalytic enzyme" without appropriate antecedent basis. In response, Applicant has amended claim 1 to provide antecedent basis.

Claim 11 was rejected as vague for use of the phrase "the diffusion medium" without proper antecedent basis. In response, Applicant has amended claim 2 to recite use of a diffusion medium in the method of claim 1 and has amended claim 11 to depend from claim 2 in place of claim 1. Support for amended claim 2 is found throughout the application, especially in the description of Figure 2 at page 13, starting at line 23, as well as in Figure 2 itself. Applicant also directs the Examiner's attention to claim 1 of the parent patent.

Claim 12 was rejected as vague for reciting "the diffusion medium" and "the electrocatalytic enzyme" without antecedent basis. In response, Applicant believes that the amendment to claims 2 avoids this ground of rejection in that claim 12 has been amended to depend from claim 2.

## **Rejection Under 25 U.S.C. 102**

Claims 1 and 11 were rejected under 35 U.S.C. 102(e) as anticipated by Heller et al. (U.S. Pat. No. 6,251,260, issued June 2001) in light of Keen et al (U.S. Pat. No. 6,060,327, issued 9 May 2000).

The Examiner contends that Heller et al disclose, as one example, a glucose sensor that includes a working electrode with a film that has a redox polymer that electrically connects reaction centers of an enzyme (i.e., a binder), such as glucose oxidase, to the electrode.

In response, Applicant notes that claim 1 recites use of a working electrode and a reference electrode wherein the determination can be performed using a single working electrode (plus the reference electrode) and does not require any additional electrodes and wherein the analyte is selected from an antigen, a hapten and an antibody (the latter recitation was originally in claim 2).

Conversely, Heller et al recite 2 types of embodiments:

1. The embodiment of Figure 1, which comprises a working electrode, a counter electrode and a reference electrode (see Figure 1 of Heller et al as well as column 5, line 66, over to column 6, line 2). Applicant's method does not employ a counter electrode but requires only a single working electrode and a reference electrode.

2. Other embodiments, wherein the reference electrode is omitted or a counter/reference electrode is used (see column 6, lines 2-4). If the reference electrode is omitted, a counter electrode is still present, whereas if the counter/reference electrode is used, a counter electrode is still present. Consequently, Heller et al do not disclose any embodiment wherein the counter electrode is not present, i.e., there is no teaching of use of a single working electrode and a reference electrode without a counter electrode.

Applicant believes that the Examiner will recognize that the sensor of Figure 1 of Heller et al is just a transistor (or triode), where the "reference electrode" is the emitter, the "working electrode" is the absorber and the "counter electrode" is the "control electrode" with the latter acting like a switch. Thus, current should flow when the counter (or control) electrode is on, for example. However, Applicant's claim 1 does not employ such a control electrode.

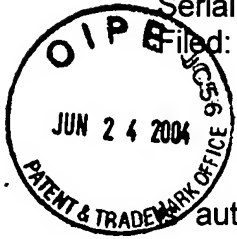
It is established Patent Law that "Anticipation requires the presence in a single prior art reference disclosure of each and every element of the claimed invention, *arranged as in the claim.*" See: *Lindemann Maschinenfabrik GmbH v. American Hoist & Derrick Co.*, 221 USPQ 481, 485 (Fed. Cir. 1984) (emphasis added).

Here, the Examiner has tried to match up elements of the reference with those of Applicant's claim 1 but has not shown how they operate together to produce the claimed method.


Further, the rejection relies on the Keen patent for a showing that the readings of the two electrodes can be compared for the determination of analyte. Applicant notes that more than one reference cannot be used to show anticipation and that the Examiner appears to be basing the rejection on combining the two references, which would be a section 103(a) rejection. However, in view of the amendments to claim 1 and the above arguments, Applicant does not believe that the combination of Heller et al and Keen et al render the invention of claim 1 unpatentable, regardless of how these references are applied.

Applicant respectfully requests that the Examiner reconsider claims 1-13 in light of the foregoing arguments.

Serial No. 10/023,797  
Filed: 17 December 2001



No fee is believed due in making this response. If any fee is due, the Commissioner authorized to charge payment of such fee, or credit any overpayment, to Deposit Account No. 03-0678.

<u>FIRST CLASS CERTIFICATE</u>	
I hereby certify that this correspondence is being deposited today with the U.S. Postal Service as First Class Mail in an envelope addressed to:	
Commissioner for Patents P. O. Box 1450 Alexandria, VA 22313-1450	
 Alan J. Grant, Esq.	<u>6/22/04</u> Date

Respectfully submitted,



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